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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,290	03/03/2004	Frank S. D'Amelio SR.	45437	3540

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EXAMINER

ROBERTS, LEZAH

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/791,290	Applicant(s) D'AMELIO ET AL.	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 9-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 9-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims

Claim Rejections - 35 USC § 112 (New Rejection)

Claims 1-7 and 9-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are indefinite insofar as the basis for the percent calculation is not set forth, e.g., percent by weight based on the total weight of the composition, percent by volume based on the volume of the carrier, etc. See Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite unless the particular method of measurement is recited.) The percent calculation must either be clearly defined (percent based on bioactive component) within the specification or set forth within the claim. Furthermore the claims need to indicate the total of the percentages, i.e., total of 100 percent.

Claim Rejections - 35 USC § 103 - Obviousness

1) Claims 1-9, 11, 12-17, 19-20, 22-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosbab (US 2001/0031744) in view of Close (US 2002/0044977). The rejection is maintained in regards to 1-7, 9, 11, 12-17, 19-20, 22-25 and 27-29. Claim 8 has been cancelled.

Applicant argues the present invention is directed to the discovery that a composition containing an extract of Centipeda genus, coenzyme Q10, aloe vera and folic acid are particularly effective in inhibiting the growth of oral bacteria. The claims are amended to recite the relative amounts of the components that are effective in inhibiting the growth of bacteria. Kosbab does not disclose the claimed amounts of the coenzyme Q10, aloe vera and folic acid. In regards to Close, the reference also fails to disclose the relative amount of the Centipeda genus extract, coenzyme Q10, aloe vera and folic acid. Accordingly, it would not have been obvious to one of ordinary skill in the art to combine the components in the relative amounts as claimed. These arguments are not persuasive.

The relative amounts read on a 1:1 ratio in the case of all components when the weight percent is 10% in the case of claim 10, 0.5 in the case of claims 12 and 22. Alternatively, even if the components are not in a 1:1 ratio and absent of unexpected results, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955).

2) Claims 1-9, 11, 12-16, 19-20, 22-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Close (US 2002/0044977) in view of Masterson et al. (US 6,200,550). The rejection is maintained in regards to claims 1-7, 9, 11, 12-17, 19-20, 22-25 and 27-29. Claim 8 has been cancelled.

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Applicant argues Close does not provide motivation or incentive to one of ordinary skill in the art to combine the extract of the Centipeda genus, aloe vera and Vitamin E with coenzyme Q10 and folic acid in the claimed amounts. Furthermore, Masterson et al. does not disclose or suggest the relative amounts of the coenzyme Q10 or aloe vera, and thus provides no motivation or incentive to combine the components in the claimed amounts with the components disclosed in Close. This argument is not persuasive.

The combination of the two references encompasses the amounts disclosed by Applicant. Masterson et al. disclose the components in concentrations that encompass the instant claims. Normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art to determine workable conditions motivated by the desire to obtain optimal results, as supported by cited precedent.

3) Claims 1, 4-5, 8-9, 11-13, 15, 17, 20-25 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Romanowski et al (US 2005/0158252). The rejection is maintained in regards to claims 1, 4-5, 9, 11-13, 15, 17, 20-25 and 27-29. Claim 8 has been cancelled.

Applicant argues the claims are directed to a composition and method and recited the relative amounts of the Centipeda genus, coenzyme Q10, aloe vera and folic

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acid. The combination of these components in the claimed amounts is particularly effective in inhibiting the growth of oral bacteria. Romanowski et al. provide no suggestion of the relative amounts of the claimed components in the specifically claimed combination. This argument is not persuasive.

Applicant does not provide any unexpected results that support this particular combination of components in the claimed amounts effectively inhibits the growth of oral bacteria. Furthermore the relative amounts read on a 1:1 ratio in the case of all components when the weight percent is 10% in the case claim 10, 0.5 in the case of claims 12 and 22. Additionally even if the amounts are not in a 1:1 ratio and absent of unexpected results, normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find workable conditions generally involves the application of no more than routine skill in the art. In re Aller 105 USPQ 233, 235 (CCPA 1955). It would have been obvious to one of ordinary skill in the art motivated by the desire to find workable conditions to obtain the desired effect.

Allowable Subject Matter

Claims 10, 18, 21 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim, any intervening claims and overcoming the 112 issues of indefiniteness. The prior art provides no motivation for selecting or combining all the components in the recited amounts. The combination of the ingredients appears to have

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a synergistic effect that inhibits the growth of bacteria as well as promotes cell renewal of the gum tissue and reduces inflammation.

Claims 1-7 and 9-29 are rejected.

Claims 10, 18, 21 and 26 are objected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lezah Roberts
Patent Examiner
Art Unit 1614



Frederick Krass
Primary Examiner
Art Unit 1614

